

**TARTER KRINSKY & DROGIN**

*Counsel for Ad Hoc Committee of NAS Children*

1350 Broadway, 11<sup>th</sup> Floor

New York, NY 10018

Tel: (212) 216-8000

Scott S. Markowitz, Esq.

Rocco A. Cavaliere, Esq.

Michael Z. Brownstein, Esq.

Email: [smarkowitz@tarterkrinsky.com](mailto:smarkowitz@tarterkrinsky.com)

Email: [rcavaliere@tarterkrinsky.com](mailto:rcavaliere@tarterkrinsky.com)

Email: [mbrownstein@tarterkrinsky.com](mailto:mbrownstein@tarterkrinsky.com)

UNITED STATES BANKRUPTCY COURT  
SOUTHERN DISTRICT OF NEW YORK

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In re:

PURDUE PHARMA L.P., *et al.*,

Debtors.<sup>1</sup>

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:  
: Chapter 11  
:  
: Case No. 19-23649 (RDD)  
:  
: (Jointly Administered)  
:

**DECLARATION OF SCOTT R. BICKFORD, ESQ. IN SUPPORT OF THE  
AD HOC COMMITTEE OF NAS CHILDREN'S REPLY TO THE UNITED STATES  
TRUSTEE'S OBJECTION TO THE FEE SETTLEMENTS INCLUDED IN THE SIXTH  
AMENDED JOINT CHAPTER 11 PLAN OF REORGANIZATION OF PURDUE  
PHARMA L.P. AND ITS AFFILIATED DEBTORS**

Under 28 U.S.C. § 1746, I, Scott R. Bickford, declare under the penalty of perjury that  
the following is true and correct to the best of my knowledge, information, and belief:

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<sup>1</sup> The Debtors in these cases, along with the last four digits of each Debtor's registration number in the applicable jurisdiction, are as follows: Purdue Pharma L.P. (7484), Purdue Pharma Inc. (7486), Purdue Transdermal Technologies L.P. (1868), Purdue Pharma Manufacturing L.P. (3821), Purdue Pharmaceuticals L.P. (0034), Imbrium Therapeutics L.P. (8810), Adlon Therapeutics L.P. (6745), Greenfield BioVentures L.P. (6150), Seven Seas Hill Corp. (4591), Ophir Green Corp. (4594), Purdue Pharma of Puerto Rico (3925), Avrio Health L.P. (4140), Purdue Pharmaceutical Products L.P. (3902), Purdue Neuroscience Company (4712), Nayatt Cove Lifescience Inc. (7805), Button Land L.P. (7502), Rhodes Associates L.P. (N/A), Paul Land Inc. (7425), Quidnick Land L.P. (7584), Rhodes Pharmaceuticals L.P. (6166), Rhodes Technologies (7143), UDF L.P. (0495), SVC Pharma L.P. (5717) and SVC Pharma Inc. (4014). The Debtors shall include their affiliates and other entities under their control. The Debtors' corporate headquarters is located at One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901.

1. This declaration (“**Declaration**”) is submitted in support of *The Ad Hoc Committee of NAS Children’s Reply* (the “**Reply**”) to the *United States Trustee’s Objection to the Fee Settlements Included in Sixth Amended Joint Chapter 11 Plan of Reorganization of Purdue Pharma L.P. and its Affiliated Debtors*.

2. I am an attorney in good standing admitted to practice in the State of Louisiana. I make this Declaration based on my own personal knowledge and belief, and upon documents and information available to me as member of and counsel to the Ad Hoc Committee of NAS Children (the “**NAS Committee**”). Capitalized terms used but not defined herein shall have the meaning given to such term in the Reply or the *Sixth Amended Joint Chapter 11 Plan of Reorganization of Purdue Pharma L.P. and Its Affiliated Debtors, dated July 14, 2021* [Docket No. 3185], as the case may be.

**A. Background**

3. The three member NAS Committee, and their designees, have been the sole advocate of the interests of NAS Children both individual and in the abatement settlement in the Chapter 11 Cases, and have acted on behalf of the interests of a group of laws firms<sup>2</sup> (the “**NAS Attorney Law Group**”) collectively representing the NAS Children. I have been a member of the NAS Committee since its inception

4. The NAS Attorney Group represents approximately 3,500 NAS children and their caregivers who are located throughout the country. Because the majority of these children were

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<sup>2</sup> The NAS Attorney Law Group consists of the following firms: Bart Bernard, P.A, Calvin C. Fayard, Jr. APC, Clayborne, Sabo and Wagner, LLP, Cooper Law Firm, LLC, Creadore Law Firm, P.C., Johnson Gray, LLC, Kent Harrison Robbins, P.A., LawCo USA, PLLC., Levenfeld Pearlstein, LLC, Lowe Stein Hoffman Allweiss & Hauver, LLP, Marioneaux & Williams, LLC, Markle DeLaCruz, LLP, Martzell Bickford & Centola, APC, MacFarlane Ferguson & McMullen, P.A., The Law Office of Stephen P. New, Perrin, Landry, deLaunay, Dartez & Ouellet, Piscitelli Law Firm, Porteous Hainkel & Johnson, LLP, Ron Austin & Associates, LLC, Schonekas, Evans, McGoey & McEachin, L.L.C, Sherrard Roe Voigt & Harbison, PLC, Thompson Barney PLLC, and Winch Law Firm, LLC.

born to a mother with an opioid dependence problem, the family situations are not ideal. Approximately half of these clients are in the care and custody of their grandparents or other family members, some have been adopted, and some are with their birth parents.

5. To fully understand the impact of *in utero* opioid exposure on NAS Children and their caregivers, the NAS Committee spent thousands of hours preparing and conducting interviews of hundreds of caregivers to identify patterns of acute and long-term complications; treatment for opioid withdrawal in infants; and social, educational, and interventional services used by its members' clients to address cognitive delays, developmental issues, and other social needs.

6. The NAS Committee also identified a group of member clients who, energized by its efforts, developed a coalition of stakeholders who met regularly and provided feedback on the needs of its client population. The NAS Committee provided resources to this group, met with them regularly and used their feedback in developing an abatement fund to reach those who are often beyond the reach of governmental entities (the "**NAS Abatement Plan**"). The NAS Abatement Plan was the starting point for what eventually became the NAS Monitoring Trust. One of the revelations of client outreach was the realization that there is no national standard of care or protocol for families, physicians, or educators to follow to make sure that NAS Children are appropriately and timely evaluated for the constellation of delays/disabilities that frequently exist in the NAS population. Absence of a national standard of care is particularly profound as most NAS Children are being raised by their grandparents, long out of the loop of child rearing. Social stigma attachments to the birth mothers and these children also created barriers to reaching out for education and medical services. These two findings, the lack of standards and

the stigma associated with rearing NAS Children, are primary issues the NAS Monitoring Trust intends to address.

7. To ensure that its efforts reached caregivers of children with NAS outside of the NAS Committee's client population, the NAS Committee monitored various online NAS support groups with thousands of caregivers, and collaborated with leaders of those groups to provide educational opportunities to their members about NAS and the ongoing opioid bankruptcy proceedings. The NAS Committee hosted in-person and virtual town-hall meetings with NAS caregivers to learn more about their experience caring for a child with NAS.

8. To better understand the work being done to support families with NAS, the NAS Committee developed working relationships with representatives from a number of non-profit organizations serving children and families impacted by NAS, including the March of Dimes, Child Welfare League of America, National Association for Children of Addiction, SAFE Project, Catholic Committee of Appalachia, Love on Wheels, and Jason's House.

9. The NAS Committee also learned a great deal about the social stigma attached to this population which makes it difficult to identify children with NAS and address their significant needs. In fact, many families avoid testing for cognitive and developmental delays associated with NAS because they do not want their children to be labeled, resulting in missed opportunities for early intervention. This social stigma is one of the problems the NAS Committee hopes the NAS Monitoring Trust will seek to address.

10. The NAS Committee expended significant resources retaining a team of world-class experts with experience in NAS, child development, addiction, pain management, healthcare, and economics. These experts include Dr. Rahul Gupta (Chief Medical Officer of the March of Dimes); Dr. Kanwaljeet S. Anand (Stanford University Professor of Pediatrics

(Pediatric Critical Care) and of Anesthesiology, Perioperative And Pain Medicine); Dr. Charles L. Werntz III (board certified preventive medicine physician); Dr. Vyvyan Howard (fetal pathologist and toxicologist); Elizabeth Davis (life care planner); Dr. Gregory Skipper (addiction psychiatry); Dr. Harvey S. Rosen (economist); Dr. Paul Keckley (healthcare researcher and policy analyst); and Herb Kuhn (President and CEO of the Missouri Hospital Association). All of these individuals assisted in advocating for and developing what ultimately became the NAS Monitoring Trust.

11. Recognizing that there are numerous aspects of injuries arising from *in utero* opioid exposure, two, one acute and one chronic, are particularly prominent. The first and most well-recognized is withdrawal - that the baby while in utero becomes dependent on the opioids and once separated from the placenta no longer receives the opioid exposure. This results in neonates being weaned by continued but diminishing opioid administration. This usually includes extended acute care hospitalization. Common withdrawal symptoms include gastrointestinal issues, nervous system irritability, and temperature instability. In severe cases, NAS newborns may also experience seizures. On average, an NAS newborn spends more days in the hospital and typically in the neonatal intensive care unit (“NICU”) than a non-NAS newborn. The costs associated with this initial hospitalization are very high. Because there is no recognized standard of care for weaning these children, it is anticipated that the NAS Monitoring Trust will fund grants seeking to develop and fast track a standard of care. It is hoped that this will reduce costs going forward.

12. The second well recognized injury arises from the failure to fully understand that chronic injuries arise from *in utero* opioid exposure due, in part to the effect of opioids on development of bone and organ structures, including the brain. This failure contributes to the

overall incorrect perception that once discharged from the hospital after birth (and weaned from opioids), the baby was otherwise healthy. Therefore, infants exposed to opiates in the womb have a propensity to suffer long-term consequences, such as developmental delays, speech impairment, vision problems, motor problems, and behavioral or learning problems. Indeed, it is this constellation of injuries that makes NAS such a tenacious problem for healthcare providers, families, educators, and the like.

13. While the effects of opioid use in adults is well-known and published, the long-term effects of opioid exposure in the womb is far less studied or understood. The NAS Committee is convinced that NAS children have not and are not receiving the study and services required to fully understand their injuries.

14. A reasonable review of this history reveals that the NAS population was late to be identified and late to receive services. Socialization and learning problems left undiagnosed or treated before these children are of school age is, may be in most cases, far too late. There is no standard of care for weaning, nor for what interventions these children should be examined for and when.

15. Other damages to the NAS Children reach far beyond the weeks spent withdrawing from opioids. Statistically significant numbers of these children are born with latent heart defects, spina bifida, and congenital malformations like cleft palate, club foot, and anklioglossia (tongue-tie), all requiring painful and expensive surgeries.

16. One of the NAS Committee's important achievements in the mediation process was to educate and convince the other participants that these non-acute injuries were indeed related to the in utero exposure and that standards of care needed to be developed to identify them early on.

**B. The MDL**

17. To bring the plight of the NAS Children to the nation's attention and to seek recovery for such children notwithstanding the efforts to delegitimize such claims, legal representatives for the NAS Committee and their associates are responsible for filing multiple complaints in multiple states on behalf of NAS Children against certain of the Debtors and other manufacturers and suppliers seeking relief for NAS Children in the form of abatement and medical surveillance, including an Ohio Class and a California Class which was converted to a national class, for: (1) the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961, *et seq.* and/or state law equivalents; (2) nuisance; (3) negligence; (4) civil conspiracy; and (5) violations of state consumer protection statutes.

**C. Discovery**

18. There unfortunately has been a dearth of discovery regarding what the pharmaceutical industry knew about prenatal opioid exposure and when and how they acquired that knowledge. Further it is not evident how that information once obtained was communicated to front line medical doctors including obstetricians, gynecologists and pediatricians. In connection with the Discovery Pleadings, for the last sixteen months, the NAS Committee has engaged in discovery (both written and depositions) with Purdue, including appearing at court hearings and attending almost a dozen "meet and confers" with the various parties in the case, including the Debtors, the Sackler family, and representatives of the so-called IACs, focusing on "Scientific Information." To date, the NAS Committee has employed highly sophisticated and expensive data search tools and techniques to competently navigate the more than 2.5 terabytes of data it has received from Debtors and producing parties, like Sackler Sides 'A' and 'B' and Mundipharma.

19. Specifically, it has reviewed:

- a. dozens of pre-clinical and clinical animal research studies;
- b. various studies regarding good laboratory practices (“**GLP**”) and non-GLP (including the terms and conditions governing agreements with third-party testing); as well as underlying governing practices and protocols concerning conduct of studies and ownership of studies and maintenance and control of research data
- c. the actual underlying lab reports containing the entries made by lab assistants;
- d. draft and final versions of new drug applications, investigatory new drug applications, and abbreviated new drug applications, relating to synthetic opioids like oxycodone and hydromorphone;
- e. numerous periodic safety update reports;
- f. communications with regulators, both domestic and foreign, regarding labeling language;
- g. data preceding 2000 (and Y2K document retention/management protocols), and post-2000, concerning Debtors’ internal records concerning drug research and studies conducted in-house, outside laboratories; and related persons, like the Mundipharma universe of businesses;
- h. and cataloged data (obtained from tens of millions of pages), and created a timeline of internal entries concerning observations, cautionary language and the like, relating to fetal exposure to opioids; and
- i. and tracked the evolution of the entries in terms of usage of ‘proscription’ language as well as ‘qualified’ language.

20. Currently, the NAS Committee is performing a comparative analysis of the ‘internal’ messaging (e.g., information maintained in the company core data sheets) versus the ‘external’ messaging (e.g., information disseminated in physician labeling and patient medication guide).

21. The information collected and examined by the NAS Committee has provided a greater understanding of NAS which the NAS Committee believes will help guide the NAS Monitoring Trust in making its grants and has to the public at large as many of the documents



will be included in the document repository contemplated under the Plan, which will undoubtedly help persons engaged in research and development of abatement programs and for enhancing general awareness of risks, and consequences, of in utero exposure to opioids.

**D. Purdue Mediation**

22. In its role as a Mediation Party, the NAS Committee and its advisors spent hundreds, if not thousands, of hours preparing for and attending numerous mediation sessions. The NAS Committee's participation was twofold – seeking funding for the NAS Abatement Plan to assist those who are often beyond the reach of governmental entities and to negotiate compensation for the NAS personal injury victims (the “**NAS PI Plan**”).

23. The NAS Committee's initial focus was to educate the Mediators (as defined in the Order Appointing Mediators) and the Mediation Parties about NAS and injuries caused by in utero opioid exposure and the need for the NAS Abatement Plan. The NAS Committee, with the assistance of its experts:

- a. Prepared videos and other presentation materials;
- b. Developed an extensive library of medical and scientific research, government legislation, policies, and programs pertaining to NAS;
- c. Reviewed a substantial number of scientific journal articles on the topics of NAS, treatment of NAS, and maternal substance abuse during pregnancy and at the time of childbirth;
- d. Researched genetic predispositions to addiction in addition to the long-term effects of opioid use, including changes in behavior and neural function as well as mitochondrial abnormalities;
- e. Scoured the scientific literature for information pertaining to specific opioid medications and their effects on human health and bodily function; and
- f. Researched scientific literature analyzing the treatment of opioid addiction and NAS. This research was not limited to contemporary scientific literature; rather, literature available at the time pharmaceutical companies began distributing opioid medications was also reviewed.

24. The NAS Committee negotiated a groundbreaking agreement to create an abatement fund in “Phase 1” of the mediation, along with a process to distribute such funds. To achieve this result took thousands of hours of attorney and expert time. The NAS Monitoring TDP was heavily negotiated by the various Mediation Parties and no party has objected to such TDP since it was filed.

25. The NAS Committee participated in countless mediation sessions and until May, 2021 was unable to achieve any meaningful progress. The NAS Committee proposed numerous proposals (including TDPs) to the mediators and the PI Ad Hoc. The vast majority of NAS Children would not have received a distribution under the complex scoring grid described in the disclosure statement accompanying each of the first three versions of the plan and any NAS Children that did qualify would have mostly likely received the lowest gross distribution, \$3,500.

Respectfully submitted this 5th day of August, 2021:

/s/ Scott R. Bickford

Scott R. Bickford, Esq.

**MARTZELL, BICKFORD & CENTOLA**

Scott R. Bickford (LA 1165)

Spencer R. Doody (LA 27795)

338 Lafayette Street

New Orleans, LA 70130

Telephone: 504-581-9065

Facsimile: 504-581-7635

[sbickford@mbfirm.com](mailto:sbickford@mbfirm.com)

[srd@mbfirm.com](mailto:srd@mbfirm.com)

[usdcndoh@mbfirm.com](mailto:usdcndoh@mbfirm.com)